DIANEAL PD-2 WITH DEXTROSE - dextrose hydrous, sodium chloride, sodium lactate, calcium chloride and magnesium chloride injection, solution

Baxter Healthcare Corporation

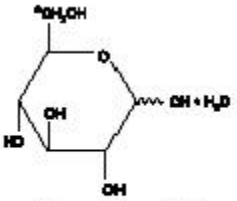
DESCRIPTION

Dianeal® PD-2 peritoneal dialysis solutions are sterile, nonpyrogenic solutions in UltraBag™ containers for intraperitoneal administration only. They contain no bacteriostatic or antimicrobial agents.

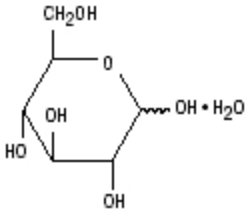
UltraBag™ containers are designed with an integrated “Y” set and drain container for infusion and drainage of Dianeal® PD-2 when disconnection of the “Y” set from the transfer set during dwell is desired.

Composition, calculated osmolarity, pH, and ionic concentrations are shown in the following table.

	Composition/100mL							Ionic Concentration (mEq/L)					How Supplied			
	Dextrose Hydrous, USP	Sodium Chloride, USP ($NaCl$)	Sodium Lactate ($C_3H_5NaO_3$)	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)	**OSMOLARITY (mOsmol/L) (calc)**	**pH**	Sodium	Calcium	Magnesium	Chloride	Lacate	Fill Volume (mL)	Container Size (mL)	Code	NDC
Dianeal®PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose	1.5 g	538 mg	448 mg	25.7 mg	5.08 mg	**346**	5.2 (4.0 & to 6.5)	132	3.5	0.5	96	40	1500 2000 2500 3000	2000 2000 3000 5000	5B9865 5B9866 5B9868 5B9857	0941-0426-51 0941-0426-52 0941-0426-53 0941-0426-55
Dianeal®PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose	2.5 g	538 mg	448 mg	25.7 mg	5.08 mg	**396**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	1500 2000 2500 3000	2000 2000 3000 5000	5B9875 5B9876 5B9878 5B9858	0941-0427-51 0941-0427-52 0941-0427-53 0941-0427-55
Dianeal®PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose	4.25 g	538 mg	448 mg	25.7 mg	5.08 mg	**485**	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	1500 2000 2500 3000	2000 2000 3000 5000	5B9895 5B9896 5B9898 5B9859	0941-0429-51 0941-0429-52 0941-0429-53 0941-0429-55



Dextrose Hydrous, USP
(D-Glucopyranose monohydrate)



Dextrose Hydrous, USP
(D-Glucopyranose monohydrate)

The plastic container tubing set is fabricated from polyvinyl chloride (PL 146® Plastic). Exposure to temperatures above 25°C/77°F during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period. The amount of water that can permeate from inside the solution container into the overpouch is insufficient to affect the solution significantly. Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials.

CLINICAL PHARMACOLOGY

Peritoneal dialysis is a procedure for removing toxic substances and metabolites normally excreted by the kidneys, and for aiding in the regulation of fluid and electrolyte balance.

The procedure is accomplished by instilling peritoneal dialysis fluid through a conduit into the peritoneal cavity. Toxic substances and metabolites, present in high concentration in the blood, cross the peritoneal membrane into the dialyzing fluid. Dextrose in the dialyzing fluid is used to produce a solution hyperosmolar to the plasma, creating an osmotic gradient which facilitates fluid removal from the patient's plasma into the peritoneal cavity. After a period of time, (dwell time), the fluid is drained by gravity from the cavity.

The solution does not contain potassium. In situations in which there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia. **Addition of potassium chloride should be made after careful evaluation of serum and total body potassium and only under the direction of a physician.**

Clinical studies have demonstrated the use of this solution resulted in significant increases in serum CO2 and decreases in serum magnesium levels. The decrease in magnesium levels did not cause clinically significant hypomagnesemia.

INDICATIONS AND USAGE

Dianeal® PD-2 peritoneal dialysis solutions in UltraBag™ containers are indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.

CONTRAINDICATIONS

None known.

WARNINGS

Not for Intravenous Injection.

Use aseptic technique. Contamination of Luer lock connector may result in peritonitis.

An improper clamping sequence may result in infusion of air into the peritoneum.

Peritoneal dialysis should be done with great care, if at all, in patients with a number of conditions, including disruption of the peritoneal membrane or diaphragm by surgery or trauma, extensive adhesions, bowel distention, undiagnosed abdominal disease, abdominal wall infection, hernias or burns, fecal fistula or colostomy, tense ascites, obesity, large polycystic kidneys, recent aortic graft replacement, lactic acidosis, and severe pulmonary disease. When assessing peritoneal dialysis as the mode of therapy in such extreme situations, the benefits to the patient must be weighed against the possible complications.

An accurate fluid balance record must be kept and the weight of the patient carefully monitored to avoid over or under hydration with severe consequences, including congestive heart failure, volume depletion, and shock.

Excessive use of Dianeal® PD-2 peritoneal dialysis solution with 4.25% dextrose during a peritoneal dialysis treatment can result in significant removal of water from the patient.

Stable patients undergoing maintenance peritoneal dialysis should have routine periodic evaluation of blood chemistries and hematologic factors, as well as other indicators of patient status.

If the resealable rubber plug on the medication port is missing or partially removed, do not use product.

After removing overpouch, check for minute leaks by squeezing container firmly. If leaks are found, discard the solution because the sterility may be impaired.

After the pull ring has been removed from the outlet, check for broken connector frangible seal as evidenced by continuous fluid flow from port. A few drops of solution within the connector or protector cap may be present. If a continuous stream or droplets of fluid are noted, discard solution because sterility may be impaired.
During solution drainage, fibrin strands may be observed in the solution and may become attached to the connector frangible closure. In occasional instances, partial or complete obstruction of draining may occur. Manipulation of the connector frangible closure in the tubing may free the fibrin obstruction.

PRECAUTIONS

General
Do not administer unless solution is clear.
Aseptic technique must be used throughout the procedure and at its termination in order to reduce the possibility of infection.
Significant losses of protein, amino acids and water soluble vitamins may occur during peritoneal dialysis. Replacement therapy should be provided as necessary.
When prescribing the solution to be used for an individual patient, consideration should be given to the potential interaction between the dialysis treatment and therapy directed at other existing illnesses. For example, rapid potassium removal may create arrhythmias in cardiac patients using digitalis or similar drugs; digitalis toxicity may be masked by elevated potassium or magnesium, or by hypocalcemia. Correction of electrolytes by dialysis may precipitate signs and symptoms of digitalis excess. Conversely, toxicity may occur at suboptimal dosages of digitalis if potassium is low or calcium high. Azotemic diabetics require careful monitoring of insulin requirements during and following dialysis with dextrose containing solutions.

Laboratory Tests
Serum electrolytes, magnesium, bicarbonate levels and fluid balance should be periodically monitored.

Carcinogenesis and Mutagenesis and Impairment of Fertility
Long term animal studies with Dianeal® PD-2 peritoneal dialysis solution have not been performed to evaluate the carcinogenic potential, mutagenic potential or effect on fertility.

Pregnancy

Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with Dianeal® PD-2 peritoneal dialysis solution. It is also not known whether Dianeal® PD-2 peritoneal dialysis solution can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dianeal® PD-2 peritoneal dialysis solution should be given to a pregnant woman only if clearly needed.

Nursing Mothers
Caution should be exercised when Dianeal® PD-2 peritoneal dialysis solution is administered to a nursing woman.

Pediatric Use
Safety and effectiveness in children have not been established.

ADVERSE REACTIONS
Adverse reactions to peritoneal dialysis include mechanical and solution related problems as well as the results of contamination of equipment or improper technique in catheter placement. Abdominal pain, bleeding, peritonitis, subcutaneous infection around the peritoneal catheter, catheter site infection, catheter blockage, difficulty in fluid removal, and ileus are among the complications of the procedure. Solution related adverse reactions may include peritonitis, electrolyte and fluid imbalances, hypovolemia, hypervolemia, hypotension, hypertension, disequilibrium syndrome, allergic symptoms, and muscle cramping.

DOSAGE AND ADMINISTRATION
Dianeal® PD-2 solutions are intended for intraperitoneal administration only.
It is recommended that adult patients being placed on continuous ambulatory peritoneal dialysis should be appropriately trained in a program which is under the supervision of a physician. Training materials are available from Baxter Healthcare Corporation, Deerfield, IL, 60015 USA to facilitate this training.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.
The frequency of treatment, formulation, exchange volume, duration of dwell, and length of dialysis should be selected by the physician responsible for and supervising the treatment of the individual patient.

To avoid the risk of severe dehydration and hypovolemia and to minimize the loss of protein, it is advisable to select the peritoneal dialysis solution with the lowest level of osmolarity consistent with the fluid removal requirements for that exchange.
Heating the dialysis solution to 37°C (98.6°F) may decrease discomfort.
Additives may be incompatible. Do not store solution containing additives.
Two liters of dialysis solution are instilled into the peritoneal cavity of adults and the peritoneal access device is then clamped. The solution remains in the cavity for dwell times of 4 to 8 hours during the day and 8 to 12 hours overnight. At the conclusion of each dwell period, the access device is opened, the solution drained and fresh solution instilled. The procedure is repeated 3 to 5 times per day, 6 to 7 days per week. Solution exchange frequency should be individualized for adequate biochemical and fluid volume control. The majority of exchanges will utilize 1.5% or 2.5% dextrose containing peritoneal dialysis solutions, with 4.25% dextrose containing solutions being used when extra fluid removal is required. Patient weight is used as the indicator of the need for fluid removal.

DIRECTIONS FOR USE
Use aseptic technique.
For complete system preparation, see directions accompanying ancillary equipment.

Preparation for Administration
1. Gather supplies.
2. Tear the container overpouch firmly down the side from top slit and remove. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity should diminish gradually.
3. Place container on work surface.
4. Uncoil tubing.
5. Inspect the patient connector to ensure the pull ring is attached. Do not use if pull ring is not attached to the connector.
6. Inspect tubing and drain container for presence of solution. If solution is noted, discard units. NOTE: Small water droplets are acceptable.
7. Squeeze container to check for leaks and broken solution frangible. Note solution flow past the frangible. Discard if container or solution frangible leaks, because sterility may be impaired.

If Supplemental Medication is Prescribed
1. Inspect container to ensure resealable rubber medication port is in place. Discard if rubber injection port is not attached to container port.
2. Put on a mask.
3. Prepare medication port according to aseptic technique.
4. Using a syringe with a 1 inch long, 19 to 25 gauge needle, puncture resealable medication port and inject medication.
5. Position container with medication port facing upward. Squeeze and tap medication port to empty solution. Mix solution by vigorously agitating container.

Administration
1. Put on mask and wash hands.
2. Insure patient transfer set is closed.
3. Break connector frangible (blue) by grasping the tubing above the top of the frangible and pulling forward and backward until the frangible separates from base. See Figures 1 and 2.
4. Remove pull ring from the patient connector.
5. Remove disconnect cap from patient transfer set. **Immediately** attach patient transfer set connector to the patient connector by twisting the connector until firmly secured.
6. Clamp solution line.
7. Break solution frangible (green) by grasping the tubing above the top of the frangible and pulling forward and backward until the frangible separates. See Figures 3 and 4.
8. Hang the new solution container.
9. Place the drainage container below the level of the peritoneum.
10. Open transfer set clamp to drain solution from peritoneum. **Warning:** During solution drainage, fibrin strands may become attached to the connector frangible closure. Manipulation of the connector frangible closure in the tubing may free any fibrin obstruction that occurs.
11. Close transfer set line clamp after drainage is complete.
12. Open solution line clamp and allow the new solution to flow into the drainage container for 5 seconds to prime line.
13. Clamp drain line.
14. Open transfer set clamp and allow the solution to flow into the peritoneum.
15. Close transfer set clamp when infusion is complete.
16. Prepare a new disconnect cap following the directions accompanying the cap.
17. Disconnect the patient transfer set connection from the UltraBag™ and attach a new disconnect cap to the transfer set.

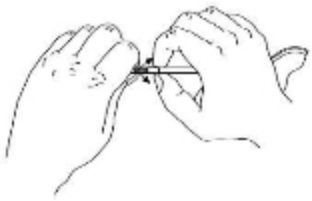


Figure 1

Figure 2

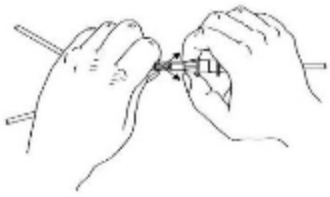


Figure 3

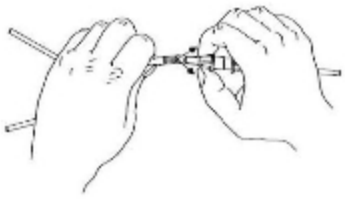
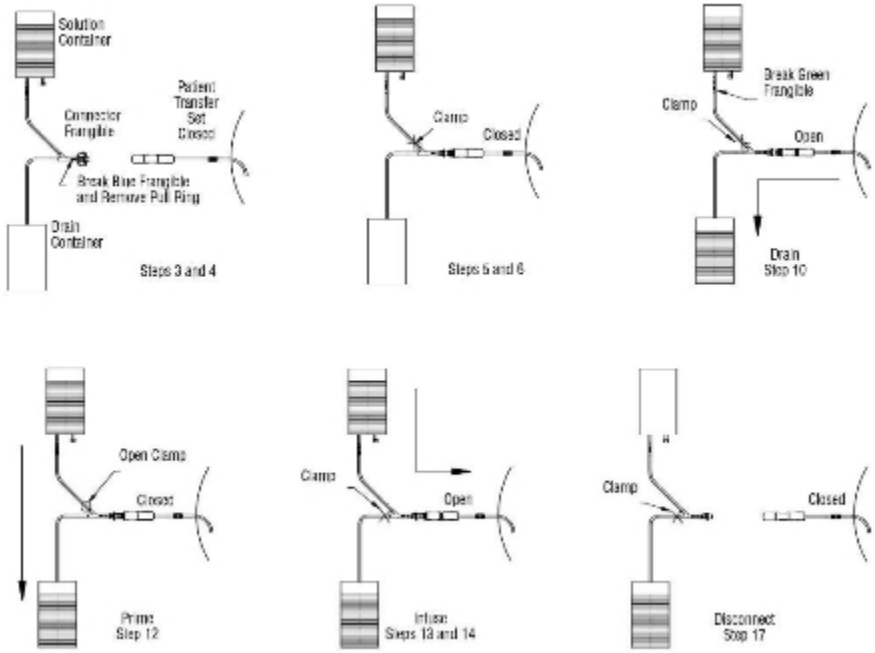


Figure 4

Administration Procedure for the UltraBag™ Container Exchange
(The Steps Refer to the Corresponding Administration Steps)



HOW SUPPLIED

Dianeal® PD-2 peritoneal dialysis solutions in UltraBag™ containers are available in nominal size flexible containers as shown in the table in the DESCRIPTION section.

All Dianeal® PD-2 peritoneal dialysis solutions have overfills which are declared on container labeling.
Freezing of solution may occur at temperatures below 0°C (32°F). Allow to thaw naturally in ambient conditions and thoroughly mix contents by shaking.
Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C/77°F).

Baxter Healthcare Corporation
Deerfield, IL 60015 USA
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